



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art. Unit : 1616
Examiner : F. Choi
Applicant(s) : Todd P. Foster, William M. Moseley, Satish K. Singh
Serial Number : 09/500246
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For : PHARMACEUTICAL IMPLANT CONTAINING IMMEDIATE
RELEASE AND SUSTAINED RELEASE COMPONENTS AND
METHOD OF ADMINISTRATION

Commissioner of Patents and Trademarks
Washington, DC 20231

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AMENDMENT

Sir:

Prior to examination, please cancel claims 1-25 and substitute therefore claims 26-47.

26. (Amended) An implant composition comprising:

(a) a first component comprising a biologically active composition contained in a first delivery vehicle capable of immediately releasing said biologically active composition upon implantation in an animal body and which is selected from the group consisting of encapsulants where the coating wall material is highly soluble in body fluids, porous or freeze-dried solid compositions, solid tablets or pellets containing a disintegrating agent which causes the solid tablet or pellet to rapidly break down when in body fluids, solid tablets or pellets containing said biologically active material in fine or micronized particle sizes[, an osmotic delivery system where the osmotic system is such that a substantial amount of the active is released upon implantation] and mixtures thereof; and

(b) a second component comprising the same biologically active composition as in component (a) contained in a second delivery vehicle capable of releasing said biologically active composition on a sustained basis upon implantation in an animal body and which is selected from the group consisting of encapsulated solutions or suspensions, biodegradable solid substances, conventional tablet/pellet ingredients, conventional tablet/pellet ingredients coated with a polymeric membrane to control release,

conventional tablets or pellets containing said biologically active material having large particle sizes, matrix-tablets based on gel-forming excipients, matrix-type systems based on non-biodegradable polymers, membrane-type systems based on non-biodegradable polymers, matrix-type systems based on biodegradable polymers, matrix-type systems implant based on lipidic excipients[, mass transfer systems based on osmotic pressure pumping through a hole in an impermeable coating] and mixtures thereof;

wherein said implant composition is implanted in an animal body by injection.

36. (Amended) A method for delivering the same biologically active material to an animal body in both a rapid release and sustained release form comprising the steps of:

(1) providing an implant comprising:

(a) a first component comprising a biologically active composition contained in a first delivery vehicle capable of immediately releasing said biologically active composition upon implantation in an animal body and which is selected from the group consisting of encapsulants where the coating wall material is highly soluble in body fluids, porous or freeze-dried solid compositions, solid tablets or pellets containing a disintegrating agent which causes the solid tablet or pellet to rapidly break down when in body fluids, solid tablets or pellets containing said biologically active material in fine or micronized particle sizes[, an osmotic delivery system where the osmotic system is such that a substantial amount of the active is released upon implantation] and mixtures thereof; and

(b) a second component comprising the same biologically active composition as in component (a) contained in a second delivery vehicle capable of releasing said biologically active composition on a sustained basis upon implantation in an animal body and which is selected from the group consisting of encapsulated solutions or suspensions, biodegradable solid substances, conventional tablet/pellet ingredients, conventional tablet/pellet ingredients coated with a polymeric membrane to control release, conventional tablets or pellets containing said biologically active material having large particle sizes, matrix-tablets based on gel-forming excipients, matrix-type systems based on non-biodegradable polymers, membrane-type systems based on non-biodegradable polymers, matrix-type systems based on biodegradable polymers,

matrix-type systems implant based on lipidic excipients[, mass transfer systems based on osmotic pressure pumping through a hole in an impermeable coating] and mixtures thereof; and

(2) injecting said implant into the animal body.

Respectfully submitted,

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Enc.: Appendix A